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By

*Janice Denison*  
(Signature of person mailing)

Janice Denison  
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Dwayne Thomas Friesen, et al.

Examiner: T. Ware

APPLICATION NO.: 09/380,825

FILING DATE: September 7, 1999

Group Art Unit: 1615

TITLE: Solubilized Sertraline Compositions

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

RESPONSE UNDER RULE 111

Responsive to the Office Action of July 30, 2002, please amend this application as follows:

D1

1. (Amended twice) A composition of matter comprising a highly soluble salt form of sertraline having a solubility in pure water of greater than 10 mgA/ml, and an amount of a solubilizing agent sufficient to produce a concentration of dissolved sertraline in a use environment containing chloride ions which is 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent.

D2

7. (Amended once) A composition of matter as defined in claim 1, wherein said solubilizing agent is selected from the group consisting of:

- 1) organic acids and organic acid salts;

D2  
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- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts

D3

10. (Amended twice) A composition of matter comprising a highly soluble salt form of sertraline having a solubility in pure water of greater than 10 mgA/ml, and an amount of a solubilizing agent sufficient to maintain, for at least 2 hours in 0.075M sodium chloride, a concentration of dissolved sertraline in a use environment containing chloride ions which is 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent.

D4

13. (Amended once) A composition of matter as defined in claim 10, wherein said solubilizing agent is selected from the group consisting of:

- 1) organic acids and organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium [carbonate] salts.

D5

15. (Amended twice) A composition of matter comprising a highly soluble salt form of sertraline having a solubility in pure water of greater than 10 mgA/ml, and an amount of a solubilizing agent sufficient to effect, *in vivo*, a  $C_{max}$  and/or an AUC which is greater by at least 10% than the  $C_{max}$  and/or AUC effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent.